in final format. Applicants submit that no new subject matter has been incorporated by way of these amendments.

- 1. A composition produced by combining therapeutically effective amounts of:
  - (a) one or more complement-fixing human, recombinant human or humanized antibodies or fragments thereof that comprise a complement-binding Fc region of a complement-fixing antibody, which specifically bind to an epitope of a mammalian myelin selected from the group consisting of galactocerebroside (GalC), O4, Myelin Associated Glycoprotein (MAG), NOGO, NI220, NI-35/250, myelin oligodendrocyte glycoprotein (MOG) and arretin; and
  - (b) sufficient complement protein to initiate complement activation, wherein said complement protein comprises at least C3 and C4 and lacks one or more of the normal complement proteins;

wherein the combination is effective to cause focal transient disruption and/or transient demyelination of mammalian neurons. (see: original claim 1& 7; pages 19-24; for (b) see page 28, lines 10-21; page 15, lines 4-16)

## 2. A composition comprising:

- (a) a first component comprising one or more complement-fixing human, human recombinant or humanized antibodies or fragments thereof that comprise a complement-binding Fc region of a complement-fixing antibody, which specifically bind to mammalian myelin epitope selected from the group consisting of a galactocerebroside (GalC), an O4, a myelin associated glycoprotein (MAG), a NOGO, a NI220, a NI-35/250, myelin oligodendrocyte glycoprotein (MOG) and an arretin; and
- (b) a second component comprising sufficient complement protein to initiate complement activation, wherein said complement protein comprises at least C3 and C4 and lacks one or more of the normal complement proteins;

wherein combining the first component and the second component in situ or in vivo produces a formulation that is effective to cause focal transient disruption and/or transient

demyelination of mammalian neurons. (see: original claim 1& 7; pages 19-24; For (b) see page 28, lines 10-21; page 15, lines 4-16)

- 3. The composition according to claim 1 or 2, wherein the second component comprises sufficient complement protein to allow complete activation of the complement cascade when the system is administered *in vivo* or *in situ*. (see page 27; line 10 13)
- 4. The composition according to any one of claims 1, 2 or 3, wherein said complement protein lacks one or more of C5, C6 and Factor B. (see page 5, lines 5 16; page 28, lines 13 16)
- 5. A two-part composition comprising:
  - (a) a first part comprising one or more complement-fixing human, human recombinant or humanized antibodies or fragments thereof that comprise a complement-binding Fc region of a complement-fixing antibody, which specifically bind to a mammalian myelin epitope selected from the group consisting of a galactocerebroside (GalC), an O4, a myelin associated glycoprotein (MAG), a NOGO, a NI220, a NI-35/250, myelin oligodendrocyte glycoprotein (MOG) and an arretin; and
  - (b) a second part sufficient complement protein to initiate complement activation, wherein said complement protein comprises at least C3 and C4 and lacks one or more of the normal complement proteins;

wherein the composition that results when the first part is combined with the second part in situ or in vivo is effective to cause focal transient disruption and/or transient demyelination of mammalian neurons. (see original claim 1& 7; pages 19-24; for (b) see page 28, lines 10-21; page 15, lines 4-16)

6. The composition according to claim 5, wherein the second part comprises sufficient complement protein to allow complete activation of the complement cascade when the system is administered *in vivo* or *in situ*. (see page 27, lines 10 – 13)

- 7. The composition according to claim 5 or 6, wherein said complement protein lacks one or more of C5, C6 and Factor B. (see page 5, lines 5 16; page 28, lines 13 16)
- 8. The pharmaceutical composition according to any one of claims 1, 2, 3 or 4, further comprising a physiologically acceptable carrier. (see original claim 15)
- 9. The composition according to any one of claims 1, 2, 3 or 4, further comprising one or more growth factors. (see original claim 12)
- 10. The composition according to any one of claims 1, 2, 3 or 4, wherein one or more of the antibodies or fragments thereof comprise or are derived from a monoclonal antibody. (see original claim 3 & 5)
- 11. The composition according to any one of claims 1, 2, 3 or 4, wherein one or more of the antibodies or fragments thereof are labeled. (see original claim 4)
- 12. The composition according to any one of claims 1, 2, 3 or 4, wherein said fragments are selected from the group consisting of a Fab, a Fab', and a F(ab')2 domain of an antibody. (see original claim 5)
- 13. The composition according to any one of claims 1, 2, 3 or 4, wherein the antibodies or fragments thereof further comprise variable regions of an Fv domain linked by a disulfide bond or by a peptide linker. (see original claim 6)
- 14. The composition according to any one of claims 1, 2, 3 or 4, wherein the complement protein is heterologous to a species to which the composition is intended to be administered. (see original claim 9)
- 15. The composition according to any one of claims 1, 2, 3 or 4, wherein the complement

protein is covalently or noncovalently attached directly or indirectly to said antibodies or fragments thereof, such that binding of said antibodies or fragments thereof to the surface of the mammalian myelin triggers an endogenous immune system attack. (see original claim 11)

- 16. The composition according to any one of claims 1, 2, 3 or 4, further comprising one or more growth factor or neurotrophic factor. (see original claim 12)
- 17. The composition according to claim 16, wherein the neurotrophic factor is FGF-1, GDNF, NGF, BDNF or NT3. (see original claims 13, 14, page 29, line 27 to page 30, line 25)
- 18. The composition as in claim 1, additionally comprising TNF (see page 31, lines 16-20)
- 19. The composition according to any one of claims 1, 2, 3 or 4, wherein the antibodies or fragments thereof comprise or are derived from a polyclonal antibody. (see original claim 3)
- 20. The composition according to any one of claims 1, 2, 3 or 4, additionally comprising one or more inhibitors of one or more components of normal complement. (page 28, line 23 to page 29, line 8)

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- 21. The composition according to any one of claims 1, 2, 3 or 4, additionally comprising:
  - (a) one or more chimeric proteins in which a first polypeptide which inhibits complement activation is linked to a second polypeptide which inhibits complement activation; or
  - (b) one or more polynucleotides encoding said one or more chimeric proteins. (see page 29, lines 10 18)
- 22. The composition according to any one of claims 1, 2, 3 or 4, additionally comprising cells

that secrete one or more nerve growth factors, neurotransmitters, neuropeptides, or enzymes involved in brain metabolism. (see page 29, line 28; page 31, lines 2-31; and page 34 line 23-32)

- 23. The composition as in claim 1, additionally comprising mononuclear phagocytes (see page 31, Lines 21-24).
- 24. The composition according to any one of claims 1, 2, 3 or 4, additionally comprising cells for transplantation wherein said cells are selected from the list comprising: neural cells, paraneural cells, genetically modified non-neural cells, genetically modified non-neural cells that secrete neurally active molecules, genetically modified foreskin fibroblast cells, cells selected from neural cell lines and cells derived from the adrenal medulla. (see page 33 line 22 line 31; page 32, line 8 to page 33 line 4; page 34, lines 25 30)
- 25. The composition according to claim 22 to 24, wherein said cells are allogenic, xenogenic or autologous. (see page 35, line 19 22)
- 26. The composition according to claim 24, wherein said neural cells are Schwann cells, astrocytes, oligodendrocytes, neurons or microglia. (see page 30, line 27 to page 31, line 15; page 24, lines 7 13)
- 27. The composition according to claim 24, wherein said paraneural cells are olfactory ensheathing glia. (see page 34, line 15-16)
- 28. The composition according to claim 24, wherein said cells are hybrid cells are prepared from somatic cell hybridization. (see page 33, line 5 line 20)
- 29. The composition according to any one of claims 22 28, wherein said cells are attached to a support matrix. (see page 34, line 1 line 5; page 35, line 15 17)

- 30. The composition according to claim 29, wherein said cells are co-cultured with glial cells and incubated with the support matrix prior to transplantation. (see page 34, line 7 line 13)
- 31. The composition according to claim 30, wherein the support matrix comprises material of synthetic or natural chemical substances or material of biological origin. (see page 35, line 28 29)
- 32. The composition according to claim 31, wherein the support matrix material is a silicon oxide, polystyrene, polypropylene, polyethylene, polyvinylidene fluoride, polyurethane, polyalginate, polysulphone, poly(tetrafluoroethylene-co-hexafluoropropylene), poly[N-(2-hydroxypropyl)methacrylamide], polyvinyl alcohol, acrylonitrile polymer, polyacrylamide, polycarbonate, polypentene, nylon, amylase, gelatin, collagen, natural polysaccharide or modified polysaccharide. (see page 35, line 29 page 36 line 3, and/or these compounds are known in the art)
- 33. The composition according to any one of claims 29 32, wherein the support matrix has an external surface that is coated with factors that promote cell adhesion, growth and/or survival. (see page 36, line 9 11)
- 34. The composition according to any one of claims 29 32, wherein the support matrix is constructed of porous material, wherein factors that promote cell adhesion, growth and/or survival are incorporated into the porous material. (see page 36, lines 14 17)
- 35. The composition according claim 33 or 34, wherein said factors are cell adhesion molecules, fibronectin, laminin, collagen, elastin, glycosaminoglycans, proteoglycans or growth factors and/or bioactive fragments thereof. (see page 36, lines 11 14)
- 36. The composition according to any one of claims 1, 2, 3 or 4, additionally comprising one or more CNS neural growth modulators. (see page 38, lines 1 19) or CNS neural growth

modulator-secreting cells (see page 39, lines 2-4).

- 37. The composition according to any one of claims 1, 2, 3 or 4, additionally comprising one or more inhibitors of myelination, wherein said inhibitors are metalloproteases, inhibitors of apoptosis and/or necrosis, inhibitors of proinflammatory cytokines, activators of antiinflammatory cytokines, antiinflammatory cytokines, activators of antioxidants, generators of antioxidants or any combination thereof. (see page 39, lines 6 12)
- 38. The composition according to any one of claims 1 37 designed for administration by a method chosen from the group comprising: injection, transplantation or perfusion (see page 31, lines13 15)
- 39. The composition according to any one of claims 1 37 designed for administration by a method that increases the level of phagocytosis. (see page 39, lines 12 14)
- 40. A method for producing a composition, comprising the step of combining
  - (a) one or more complement-fixing human, recombinant human or humanized antibodies or fragments thereof that comprise a complement-binding Fc region of a complement-fixing antibody, which specifically bind to a mammalian myelin epitope selected from the group consisting of a galactocerebroside (GalC), an O4, a myelin associated glycoprotein (MAG), a NOGO, a NI220, a NI-35/250, myelin oligodendrocyte glycoprotein (MOG) and an arretin; and

sufficient complement protein to initiate complement activation, wherein said complement protein comprises at least C3 and C4 and lacks one or more of the normal complement proteins. (see original claim 1& 7; pages 19-24; for (b) see page 28, lines 10-21; page 15, lines 4-16)

41. The method according to claim 38, wherein the complement protein is present in an amount sufficient to allow complete activation of the complement cascade when the composition is administered *in vivo* or *in situ*. (see page 27, lines 10 – 13)

- 42. A system for promoting the transient demyelination of mammalian neurons comprising a composition in at least two separate containers, wherein a first container comprises one or more complement-fixing human, human recombinant or humanized antibodies or fragments thereof that comprise a complement-binding Fc region of a complement-fixing antibody, which specifically bind to a mammalian myelin epitope selected from the group consisting of galactocerebroside (GalC), O4, Myelin Associated Glycoprotein (MAG), NOGO, NI220, NI-35/250, Myelin Oligodendrocyte Glycoprotein (MOG) and arretin, and, a second container comprises sufficient complement protein to initiate complement activation, wherein said complement protein comprises at least C3 and C4 and lack one or more of the normal complement proteins. . (see original claim 1& 7; pages 19 24; for (b) see page 28, lines 10 21; page 15, L4 16)
- 43. The system according to claim 40, wherein the second container comprises sufficient complement protein to allow complete activation of the complement cascade when the system is administered *in vivo* or *in situ*. (see page 27, lines 10 13)
- 44. Use of a composition according to any one of claims 1 39, to transiently disrupt and/or transiently demyelinate mammalian neurons and thereby promote neuron repair and/or growth in a mammal. (see original claim 16)
- 45. Use of the composition according to any one of claims 1 39, for the treatment of a neurological disorder in a mammal, wherein the composition is administered prior to, or concurrent with, cellular transplantation therapy. (see page 36, line 30 page 37, line 1)
- 46. Use of the composition according to any one of claims 1 − 39, to generate an environment within the CNS of a mammal that is permissive to growth of transplanted cells. (see original claim 25)
- 47. The use according to any one of claims 44 46, wherein said mammal has a neuron

- dysfunction. (see original claims 20 24)
- 48. The use according to claim 47, wherein the neuron dysfunction is caused by injury or trauma to the CNS. (see original claim 20)
- 49. The use according to claim 48, wherein the injury is a spinal cord injury. (see original claim 21)
- 50. The use according to claim 47, wherein the neuron dysfunction is caused by disease. (see original claim 22)
- 51. The use according to claim 50, wherein the disease is selected from the group consisting of Alzheimer's disease and Parkinson's disease. (see original claim 23)
- 52. The use according to claim 47, wherein the neuron dysfunction is chronic. (see original claim 24)
- 53. The use according to claim 44, wherein said neural growth regenerates structures lost due to injury, illness or those having incomplete or immature formation. (see page 38, line 31 32)
- 54. The use of the composition according to any one of claims 1 39 to facilitate grafting a cell in a mammal. (see page 31, line 26 to page 32, line 16)
- 55. The use according to any one of claims 44 or 54, wherein the mammal is human. (see original claim 18)
- 56. The use of one or more complement-fixing antibodies or fragments thereof, which specifically bind to an epitope of myelin, and which are labeled, to detect and monitor the efficacy of the composition to cause focal transient disruption and/or transient

demyelination of mammalian neurons. (see original claim 26)

- 57. The composition according to any one of claims 1-39, contained within a biodegradable polymer microsphere. (see page 42, lines 7-18)
- 58. The composition according to any one of claims 1 39, contained within an implant. (see page 41, lines 18 24)
- 59. The composition according to any one of claims 1 39, contained within a pump. (see page 41, line 26 to page 42, line 5)

## SECTION III: WITH REGARD TO NON-ESTABLISHMENT OF OPINION

In paragraph b, Section III of the Written Opinion, the Examiner states that original claim 26 contains confusing wording which renders the whole claim unclear. Applicants have submitted new claims 1 – 59, of which the subject matter of original claim 26 is now accorded to new claim 56, which has been amended to more precisely describe the subject matter of the invention. Applicants assert that the wording of new claim 56 clearly indicates that the labelled antibodies or fragments thereof, can be used to monitor focal transient disruption and/or transient demyelination of mammalian neurons.

In paragraph c, Section III of the Written Opinion, the Examiner states that original claim 25 is inadequately supported by the description. In particular, the Examiner contends that the wording on page 40 (lines 9-13) is inefficient at establishing that the claimed compositions are actually capable of generating an environment within the mammalian CNS that is permissive to growth of transplanted cells. Applicants have submitted new claims 1-59, of which the subject matter of original claim 25 is now accorded to new claim 46. Applicants respectfully disagree with the Examiners objection and assert that the application in its entirety is directed towards describing and demonstrating that the composition can be used to disrupt the myelin in the CNS which

generates the environment that is "relatively permissive" to growth of cells, both pre-existing and/or transplanted cells. Applicants use the term "relatively" to indicate that the environment following use of the composition is more permissive than a non-demyelinated environment.

Lines 6 – 9, page 3 describe the state of the art prior to this invention, "The use of transplanted neural cells is also of limited clinical value: although axons will be able to grow into the transplanted tissue, they will not be able to grow out of the transplanted tissue back into the CNS due to inhibitory matter in the CNS. On lines 23 - 25, page 5, Applicants also describe that "there is a need for improved methods of disrupting myelin in vivo in order to enhance regeneration of neurological tissue. The present invention provides methods that address this need." From page 29 to 39 Applicants describe how many different cell types can be transplanted into the CNS along with the demyelinating composition to enhance regeneration of neurological tissue.

Moreover, lines 11-13 on page 31 state, "demyelination renders the environment more permissive to cellular growth following Schwann cell transplantation." The text following this statement extensively describes numerous cells that can be transplanted with the composition, as described in lines 2-5 on page 34, "However, an additional embodiment is directed to transplantation of cells . . . either in vitro prior to transplant, in vivo after transplant, or both, . . . and the composition of the present invention."

## SECTION V: WITH REGARD TO NOVELTY, INVENTIVE STEP OR INDUSTRIAL APPLICABILITY

In paragraph b (iv), Section V of the Written Opinion, the Examiner contends that the subject matter of claims 1, 3, 7 - 11, 16 and 17 are not new in respect of the prior art (documents D1, D2 and/or D3).

Applicants have amended the claims to more precisely describe the subject matter of the invention.

In particular, the subject matter of original claims 3, 7-11, 16 and 17 is now dependent upon new claim 1, which is restricted to a composition, "wherein said complement protein comprises at least C3 and C4 and lacks one or more of the normal complement proteins," and is therefore novel over the prior art.

In paragraph b (v), Section V of the Written Opinion, the Examiner states that the subject-matter of claims 2, 4-6, 11-14, 18-24 and 27 may be considered to be new, as being not disclosed in the relevant state of the art.

In paragraph c (i), (ii) and (iii) of Section V of the Written Opinion, the Examiner states that the subject-matter of claims 2, 4-6, 11-14, 27 and 18 is not considered to involve an inventive step. Applicants have amended Claim the claims to more precisely describe the subject matter of the invention. Claims 2, 4-6 and 11-14 are now dependent upon new claim 1, which is restricted to a composition, "wherein said complement protein comprises at least C3 and C4 and lacks one or more of the normal complement proteins," and are therefore inventive over the prior art.

Applicants assert that no new matter has been added by way of these amendments and respectfully request that the Examiner respond to the new claims and above assertions in a favourable manner.

Respectfully submitted,

MBM & Co.

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- 1. A composition produced by combining therapeutically effective amounts of:
  - (a) one or more complement-fixing human, recombinant human or humanized antibodies or fragments thereof that comprise a complement-binding Fc region of a complement-fixing antibody, which specifically bind to an epitope of a mammalian myelin selected from the group consisting of galactocerebroside (GalC), O4, Myelin Associated Glycoprotein (MAG), NOGO, NI220, NI-35/250, myelin oligodendrocyte glycoprotein (MOG) and arretin; and
  - (b) sufficient complement protein to initiate complement activation, wherein said complement protein comprises at least C3 and C4 and lacks one or more of the normal complement proteins;

wherein the combination is effective to cause focal transient disruption and/or transient demyelination of mammalian neurons.

## 2. A composition comprising:

- (a) a first component comprising one or more complement-fixing human, human recombinant or humanized antibodies or fragments thereof that comprise a complement-binding Fc region of a complement-fixing antibody, which specifically bind to mammalian myelin epitope selected from the group consisting of a galactocerebroside (GalC), an O4, a myelin associated glycoprotein (MAG), a NOGO, a NI220, a NI-35/250, myelin oligodendrocyte glycoprotein (MOG) and an arretin; and
- (b) a second component comprising sufficient complement protein to initiate complement activation, wherein said complement protein comprises at least C3 and C4 and lacks one or more of the normal complement proteins;

wherein combining the first component and the second component in situ or in vivo produces a formulation that is effective to cause focal transient disruption and/or transient demyelination of mammalian neurons.

- 3. The composition according to claim 1 or 2, wherein the second component comprises sufficient complement protein to allow complete activation of the complement cascade when the system is administered *in vivo* or *in situ*.
- 4. The composition according to any one of claims 1, 2 or 3, wherein said complement protein lacks one or more of C5, C6 and Factor B.
- 5. A two-part composition comprising:
  - (a) a first part comprising one or more complement-fixing human, human recombinant or humanized antibodies or fragments thereof that comprise a complement-binding Fc region of a complement-fixing antibody, which specifically bind to a mammalian myelin epitope selected from the group consisting of a galactocerebroside (GalC), an O4, a myelin associated glycoprotein (MAG), a NOGO, a NI220, a NI-35/250, myelin oligodendrocyte glycoprotein (MOG) and an arretin; and
  - (b) a second part sufficient complement protein to initiate complement activation, wherein said complement protein comprises at least C3 and C4 and lacks one or more of the normal complement proteins; wherein the composition that results when the first part is combined with the second part in situ or in vivo is effective to cause focal transient disruption and/or transient demyelination of mammalian neurons.
- 6. The composition according to claim 5, wherein the second part comprises sufficient complement protein to allow complete activation of the complement cascade when the system is administered *in vivo* or *in situ*.
- 7. The composition according to claim 5 or 6, wherein said complement protein lacks one or more of C5, C6 and Factor B.
- 8. The pharmaceutical composition according to any one of claims 1, 2, 3 or 4, further comprising a physiologically acceptable carrier.

- 9. The composition according to any one of claims 1, 2, 3 or 4, further comprising one or more growth factors.
- 10. The composition according to any one of claims 1, 2, 3 or 4, wherein one or more of the antibodies or fragments thereof comprise or are derived from a monoclonal antibody.
- 11. The composition according to any one of claims 1, 2, 3 or 4, wherein one or more of the antibodies or fragments thereof are labeled.
- 12. The composition according to any one of claims 1, 2, 3 or 4, wherein said fragments are selected from the group consisting of a Fab, a Fab', and a F(ab')2 domain of an antibody.
- 13. The composition according to any one of claims 1, 2, 3 or 4, wherein the antibodies or fragments thereof further comprise variable regions of an Fv domain linked by a disulfide bond or by a peptide linker.
- 14. The composition according to any one of claims 1, 2, 3 or 4, wherein the complement protein is heterologous to a species to which the composition is intended to be administered.
- 15. The composition according to any one of claims 1, 2, 3 or 4, wherein the complement protein is covalently or noncovalently attached directly or indirectly to said antibodies or fragments thereof, such that binding of said antibodies or fragments thereof to the surface of the mammalian myelin triggers an endogenous immune system attack.
- 16. The composition according to any one of claims 1, 2, 3 or 4, further comprising one or more growth factor or neurotrophic factor.

- 17. The composition according to claim 16, wherein the neurotrophic factor is FGF-1, GDNF, NGF, BDNF or NT3.
- 18. The composition as in claim 1, additionally comprising TNF
- 19. The composition according to any one of claims 1, 2, 3 or 4, wherein the antibodies or fragments thereof comprise or are derived from a polyclonal antibody.
- 20. The composition according to any one of claims 1, 2, 3 or 4, additionally comprising one or more inhibitors of one or more components of normal complement.
- 21. The composition according to any one of claims 1, 2, 3 or 4, additionally comprising:
  - (a) one or more chimeric proteins in which a first polypeptide which inhibits complement activation is linked to a second polypeptide which inhibits complement activation; or
  - (b) one or more polynucleotides encoding said one or more chimeric proteins.
- 22. The composition according to any one of claims 1, 2, 3 or 4, additionally comprising cells that secrete one or more nerve growth factors, neurotransmitters, neuropeptides, or enzymes involved in brain metabolism.
- 23. The composition as in claim 1, additionally comprising mononuclear phagocytes.
- 24. The composition according to any one of claims 1, 2, 3 or 4, additionally comprising cells for transplantation wherein said cells are selected from the list comprising: neural cells, paraneural cells, genetically modified non-neural cells, genetically modified non-neural cells that secrete neurally active molecules,

genetically modified foreskin fibroblast cells, cells selected from neural cell lines and cells derived from the adrenal medulla.

- 25. The composition according to claim 22 to 24, wherein said cells are allogenic, xenogenic or autologous.
- 26. The composition according to claim 24, wherein said neural cells are Schwann cells, astrocytes, oligodendrocytes, neurons or microglia.
- 27. The composition according to claim 24, wherein said paraneural cells are olfactory ensheathing glia.
- 28. The composition according to claim 24, wherein said cells are hybrid cells are prepared from somatic cell hybridization.
- 29. The composition according to any one of claims 22 28, wherein said cells are attached to a support matrix.
- 30. The composition according to claim 29, wherein said cells are co-cultured with glial cells and incubated with the support matrix prior to transplantation.
- 31. The composition according to claim 30, wherein the support matrix comprises material of synthetic or natural chemical substances or material of biological origin.
- 32. The composition according to claim 31, wherein the support matrix material is a silicon oxide, polystyrene, polypropylene, polyethylene, polyvinylidene fluoride, polyurethane, polyalginate, polysulphone, poly(tetrafluoroethylene-co-hexafluoropropylene), poly[N-(2-hydroxypropyl)methacrylamide], polyvinyl alcohol, acrylonitrile polymer, polyacrylamide, polycarbonate, polypentene,

- nylon, amylase, gelatin, collagen, natural polysaccharide or modified polysaccharide.
- 33. The composition according to any one of claims 29 32, wherein the support matrix has an external surface that is coated with factors that promote cell adhesion, growth and/or survival.
- 34. The composition according to any one of claims 29 32, wherein the support matrix is constructed of porous material, wherein factors that promote cell adhesion, growth and/or survival are incorporated into the porous material.
- 35. The composition according claim 33 or 34, wherein said factors are cell adhesion molecules, fibronectin, laminin, collagen, elastin, glycosaminoglycans, proteoglycans or growth factors and/or bioactive fragments thereof.
- 36. The composition according to any one of claims 1, 2, 3 or 4, additionally comprising one or more CNS neural growth modulators or CNS neural growth modulator-secreting cells.
- 37. The composition according to any one of claims 1, 2, 3 or 4, additionally comprising one or more inhibitors of myelination, wherein said inhibitors are metalloproteases, inhibitors of apoptosis and/or necrosis, inhibitors of proinflammatory cytokines, activators of antiinflammatory cytokines, antiinflammatory cytokines, activators of antioxidants, generators of antioxidants or any combination thereof.
- 38. The composition according to any one of claims 1 37 designed for administration by a method chosen from the group comprising: injection, transplantation or perfusion

- 39. The composition according to any one of claims 1 37 designed for administration by a method that increases the level of phagocytosis.
- 40. A method for producing a composition, comprising the step of combining
  - (a) one or more complement-fixing human, recombinant human or humanized antibodies or fragments thereof that comprise a complement-binding Fc region of a complement-fixing antibody, which specifically bind to a mammalian myelin epitope selected from the group consisting of a galactocerebroside (GalC), an O4, a myelin associated glycoprotein (MAG), a NOGO, a NI220, a NI-35/250, myelin oligodendrocyte glycoprotein (MOG) and an arretin; and

sufficient complement protein to initiate complement activation, wherein said complement protein comprises at least C3 and C4 and lacks one or more of the normal complement proteins.

- 41. The method according to claim 38, wherein the complement protein is present in an amount sufficient to allow complete activation of the complement cascade when the composition is administered *in vivo* or *in situ*.
- 42. A system for promoting the transient demyelination of mammalian neurons comprising a composition in at least two separate containers, wherein a first container comprises one or more complement-fixing human, human recombinant or humanized antibodies or fragments thereof that comprise a complement-binding Fc region of a complement-fixing antibody, which specifically bind to a mammalian myelin epitope selected from the group consisting of galactocerebroside (GalC), O4, Myelin Associated Glycoprotein (MAG), NOGO, NI220, NI-35/250, Myelin Oligodendrocyte Glycoprotein (MOG) and arretin, and, a second container comprises sufficient complement protein to initiate complement activation, wherein said complement protein comprises at least C3 and C4 and lack one or more of the normal complement proteins.

- 43. The system according to claim 40, wherein the second container comprises sufficient complement protein to allow complete activation of the complement cascade when the system is administered *in vivo* or *in situ*.
- 44. Use of a composition according to any one of claims 1-39, to transiently disrupt and/or transiently demyelinate mammalian neurons and thereby promote neuron repair and/or growth in a mammal.
- 45. Use of the composition according to any one of claims 1-39, for the treatment of a neurological disorder in a mammal, wherein the composition is administered prior to, or concurrent with, cellular transplantation therapy.
- 46. Use of the composition according to any one of claims 1-39, to generate an environment within the CNS of a mammal that is permissive to growth of transplanted cells.
- 47. The use according to any one of claims 44 47, wherein said mammal has a neuron dysfunction.
- 48. The use according to claim 47, wherein the neuron dysfunction is caused by injury or trauma to the CNS.
- 49. The use according to claim 48, wherein the injury is a spinal cord injury.
- 50. The use according to claim 47, wherein the neuron dysfunction is caused by disease.
- 51. The use according to claim 50, wherein the disease is selected from the group consisting of Alzheimer's disease and Parkinson's disease.

- 52. The use according to claim 47, wherein the neuron dysfunction is chronic.
- 53. The use according to claim 44, wherein said neural growth regenerates structures lost due to injury, illness or those having incomplete or immature formation.
- 54. Use of the composition according to any one of claims 1-39 to facilitate grafting a cell in a mammal.
- 55. The use according to any one of claims 44 or 54, wherein the mammal is human.
- 56. Use of one or more complement-fixing antibodies or fragments thereof, which specifically bind to an epitope of myelin, and which are labeled, to detect and monitor the efficacy of the composition cause focal transient disruption and/or transient demyelination of mammalian neurons.
- 57. The composition according to any one of claims 1-39, contained within a biodegradable polymer microsphere.
- 58. The composition according to any one of claims 1-39, contained within an implant.
- 59. The composition according to any one of claims 1-39, contained within a pump.